DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
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May 9, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-42

Mark A. Wheeler, President
Wheeler Seafoods, Inc.
10700 Woodinville Drive
Bothell, Washington 98011

WARNING LETTER

Dear Mr. Wheeler:

We inspected your firm located at 10700 Woodinville Drive, Bothell, Washington, on January 13, 2000, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery products (Seafood HACCP regulations). A FDA 483 form (copy-enclosed) listing the deviations was presented to you at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your fresh and frozen yellowfin tuna, mahi mahi, albacore, escolar, marlin, opakapaka, and ono to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

The deviations were as follows:

1. You must have a HACCP plan to control any food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6(b). Your firm does not have a HACCP plan for fresh albacore, escolar, marlin, opakapaka, and ono to control the food safety hazard of histamines.

   During the last inspection you asked if you could add other histamine forming fish to your existing HACCP plan. To the extent that the hazards and control methods are identical, you may group products (21 CFR 123.6(b)(2).

2. You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). Your firm does not have product specifications for farmed Atlantic salmon imported from Canada. The specification must list all the appropriate safety hazards and the safety limits must be appropriate.

You must maintain records, in English, that document the performance and results of the affirmative step(s), to comply with 21 CFR 123.12(c). Your firm did not have records for farmed Atlantic salmon manufactured by [redacted]

3. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, in order to comply with 21 CFR 123.7(b). Your corrective action plan for yellowfin tuna and mahi mahi at the processing critical control point to control histamines does not include corrections for both the product and the process. This deviation was previously brought to your attention in our letter of September 17, 1999.

The above HACCP violations are not meant to be an all-inclusive list of deficiencies in your plant. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA, including the Seafood HACCP regulations and the Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food regulations in 21 CFR 110. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product and/or enjoin your firm from operating. Pertinent sections of the Act and regulations are enclosed for your review.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan and copies of your monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Robert L. Wesley, Compliance Officer, 1000 2nd Avenue, Suite 2400, Seattle, Washington 98104. If you have any questions regarding any issue in this letter, please contact Robert Wesley at 206/553-7001, extension 57.

Sincerely,

Charles M. Breen
District Director

Enclosures:
Form FDA 483
21 CFR PART 123
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: WSDA with disclosure statement